K101294

Premarket Notification [510(k)] Summary
PT2 Varian Proton Therapy System

DEC 27 2010

The following information is provided following the format of 21 CFR 807.92.

Submitter's Name:

Varian Medical Systems, Inc.
3100 Hansen Way e-110
Palo Alto, CA 94304

Contact Name: Vy Tran
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Date: 5 May 2010

Proprietary Name:

PT2 Varian Proton Therapy System

Classification Name:

Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: LHN

Common/Usual Name:

Proton Therapy System

Predicate Devices:

Proteus 235 Proton Therapy System from Ion Beam Applications S.A. (K082416).

Device Description:

PT2 Varian Proton Therapy System is a proton radiation therapy system which delivers therapeutic radiation in accordance with a physician's prescription.

The system consists of four major components,

1) Cyclotron required to generate the photon beam
2) Beam line - transports beam from the cyclotron to the required treatment room
3) Up to 4 radiation treatment rooms
4) Treatment Control room

Statement of Intended Use

PT2 Varian Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Statement of Indications for Use:

PT2 Varian Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Technological Characteristics:

See device comparison table below.

Description	IBA Proton Therapy System - Proteus 235	PT2 Varian Proton Therapy System
510(k) Number	K082416	K101294
Intended Use	The PTS is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.	PT2 Varian Proton Therapy System provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.
Indications For Use	The PTS is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.	PT2 Varian Proton Therapy System, provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.
Proton Accelerator	Isochronous Cyclotron (not superconducting)	Isochronous Cyclotron (superconducting type using helium cryogen cooling)
Treatment Particle	Proton	Proton
Cyclotron energy	230 MeV	250 MeV
Proton Energy Selection	70-230 Mev	90-230 MeV (usable energy range)
Energy Selection	Via mechanical degrader system and Energy Selection System based on magnetic deflection	Via mechanical degrader system and Energy Selection System based on magnetic deflection
Beam Transport	Standard beam optical system with quadrupoles and dipole magnets	Standard beam optical system with quadrupoles and dipole magnets
Number of Treatment Rooms	3 to 7 treatment rooms with fixed beam treatment stations or isocentric gantries.	1 to 4 treatment rooms with isocentric gantries. No fixed beam treatment stations.
Beam angle adjustment	Fixed in Fixed Beam treatment stations or adjustable via Rotating Isocentric Gantry	Adjustable via Rotating Isocentric Gantry
Beam delivery	Beam Scattering or Pencil Beam Scanning The pencil beam scanning is defined as the act of moving a charged particle beam of particular properties and/or changing one or more of the properties of that beam (e.g. Intensity (e.g. # protons/second), size (e.g. 1 sigma), position etc.)	Beam Spot Scanning in all treatment stations The beam spot scanning is defined as the act of moving a charged particle beam of particular properties from one spot to the next over the whole treatment volume and/or changing one or more of the properties of that beam (e.g. Intensity (e.g. # protons/second), position etc.). The charged particle beam stops on each spot until the predefined the proton fluence according to a prescription is reached and moves to the next spot. After one layer of spots is done the depth will be changed by the change of the energy and the next layer of spots will be executed.
Patient Positioning	6-AxisTreatment Table	6-Axis Treatment Table
Patient Position Verification System	Included	Not included
Laser positioning system	Included	Included

Summary of Performance Testing Results of verification and validation testing demonstrate that the PT2 Varian Proton Therapy System satisfies the intended use as described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Vy Tran
Official Correspondent
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

DEC 27 2010

Re: K101294
Trade/Device Name: PT2 Varian Proton Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: September 17, 2010
Received: September 22, 2010

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Indications for Use Statement

DEC 27 2010

510(k) Number: K101294
Device Name: **PT2 Varian Proton Therapy System**

PT2 Varian Proton Therapy System, provides protons for precision radiotherapy of lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101294